Exclusive: BeyondSpring's Plinabulin Reduces Bone Pain in CIN Patients

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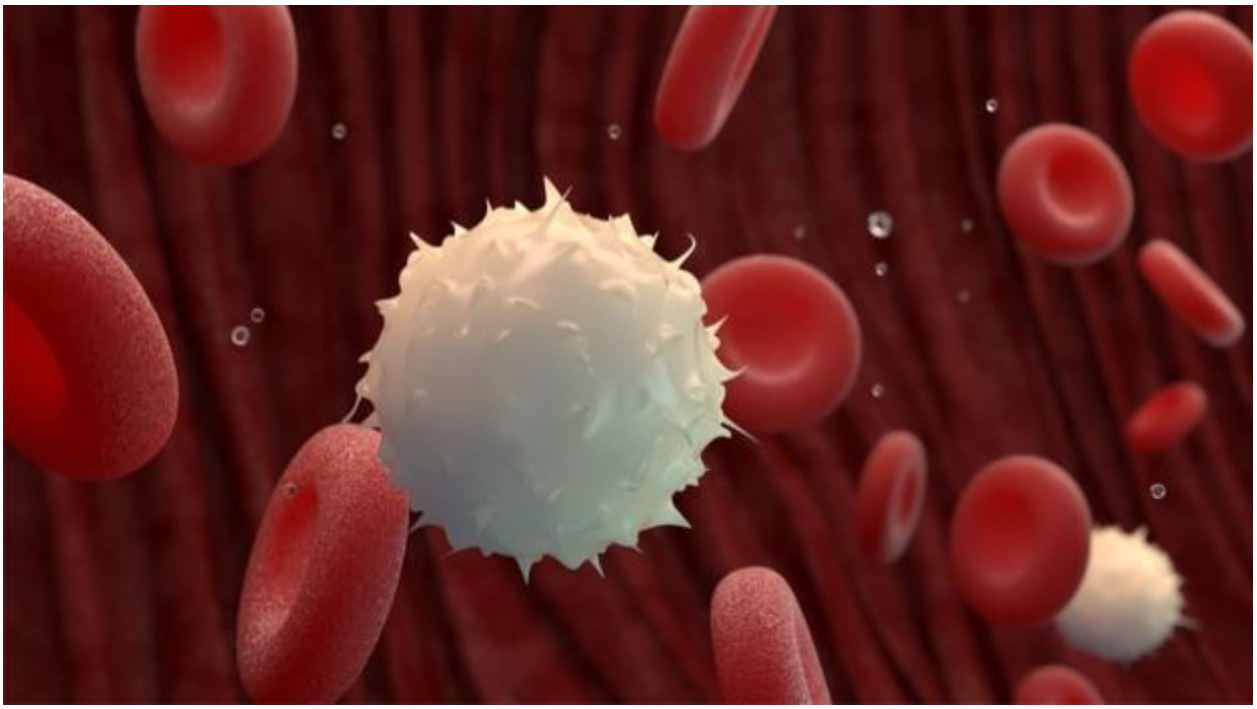

Lan Huang, chief executive officer of **BeyondSpring**, believes her company has the "secret sauce" that could provide beneficial treatment to chemotherapy-induced neutropenia, a common side effect for chemotherapy patients.

Huang is talking about her company's lead asset Plinabulin, a marine-derived small molecule that sequesters tubulin heterodimers. Plinabulin, Huang said, is a potential disruptor in treatment for these conditions. The drug is being studied as a potential therapy for the treatment of chemotherapy-induced neutropenia (CIN). BeyondSpring will take clinical data into the **American Society of Clinical Oncology** (ASCO) and show off the efficacy and safety of the therapeutic as a treatment for CIN. Neutrophils are a type of white blood cell that fights infections in the body. CIN occurs when neutrophils are not being produced due to the effects of chemotherapy. CIN increases a patient's risk of infection and disrupts their cancer treatment.

While Plinabulin was being developed as an anti-cancer agent, Huang told BioSpace that it was interesting for BeyondSpring researchers to discover the drug's effects on CIN. Current treatment for CIN prevention is G-CSF monotherapy such as Neulasta, but that has serious limitations, Huang said. In fact, many of the patients who receive high-risk chemotherapy and G-CSF monotherapy can still experience Grade 3 or 4 CIN. When these Grades of CIN appear, it forces doctors to reduce the dose of chemotherapy, thereby slowing treatment for the cancer. Doctors can also choose to discontinue the treatment process, which significantly lowers survivor outcome, she said.

Another serious concern for many patients who receive G-CSF monotherapy is a concern over bone pain. Up to 70% of patients using G-CSF monotherapy experience bone pain. Of those, 25% of patients classified the pain as severe. For those patients who describe the pain as severe, Huang said many patients refuse the standard treatment options.

"For those patients, it feels like their bones are going to explode and they often refuse treatment. Our studies show that Plinabulin can dramatically reduce the bone pain," Huang said.

At ASCO, Huang said the company will show off data that pairs Plinabulin with Neulasta and how it reduces CIN in breast cancer patients. Data showed that only 50 percent of patients treated with Plinabulin combined with 6 milligram Neulasta or Plinabulin/Neulasta combo experienced Grade 3 or 4 CIN. When it came to bone pain, BeyondSpring data showed that only 6% of patients treated with Plinabulin/Neulasta combo experienced at least one day of bone pain versus 95% of patients treated with Neulasta alone.

Huang noted that it takes about eight days for Neulasta to begin to work in the body. During those first days of treatment, she said Plinabulin is able to provide the protection the patients need.

A second abstract BeyondSpring will share at ASCO shows off how a lower dose of Neulasta paired with Plinabulin can not only provide protection against CIN but also benefit patients regarding immune suppression. Huang said it's known that Neulasta induces immune suppression. She said if the dose of Neulasta is lowered and paired with Plinabulin, the protection is still provided for patients. Following positive Phase II results, Plinabulin is currently in Phase III clinical development to increase overall survival in cancer patients.

In addition to the efficacy in CIN, Huang said Plinabulin has also shown a benefit as a second-line therapy for non-small cell lung cancer patients who have Epidermal Growth Factor Receptor (EGFR) wild type mutations. When combined with Docetaxel, Huang said the treatment is making an impact in the wild type patients. That particular mutation accounts for 70 to 85% of patients and there are currently only four approved treatment options for this, Huang said.

With the data in hand, Huang said the company is laser-focused on filing New Drug Applications with both the U.S. Food and Drug Administration, as well as China's regulatory agency, for both CIN and non-small cell lung cancer, with the EGFR wild type. The company's regulatory strategy for both indications is to seek approval in China in the fourth quarter of 2019 and then in the U.S. in 2020.

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